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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/519,193

12/21/2005

Heinrich Haas

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9629 7590 11/09/2009  
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EXAMINER

SHOMER, ISAAC

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

11/09/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/519,193	<b>Applicant(s)</b> HAAS ET AL.	
	<b>Examiner</b> ISAAC SHOMER	<b>Art Unit</b> 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 September 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 24-59 is/are pending in the application.
- 4a) Of the above claim(s) 28,33,36-53 and 55-59 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 24-27,29-32,34,35 and 54 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7 October 2009</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

Applicants' arguments, filed 14 September 2009, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 24-27, 29, 31, 32, 34, 35 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perez-Soler et al. (US Patent 5,834,012).

Perez-Soler et al. (hereafter referred to as Perez-Soler) teaches the encapsulation of camptothecin in a liposome, wherein said liposome may comprise a cationic lipid, such as DOTAP, as of Perez-Soler, column 13 lines 30-63. Perez-Soler teaches a specific embodiment wherein the ratio of DOTAP to camptothecin is 12.5:1, as of Perez-Soler, column 14 Table 2, line 39. Perez-Soler teaches that DOTAP, DOPE, and dioleoyl phosphatidylcholine (DOPC) form complexes with camptothecin, as of Perez-Soler, column 14 lines 4-7. In a separate embodiment, Perez-Soler teaches that

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the term *camptothecin* refers to camptothecin both in the lactone and the carboxy form, as of Perez-Soler, column 3 lines 28-30. Also in a separate embodiment, Perez-Soler teaches the use of DOTMA as a cationic lipid, as of Perez-Soler, column 4 lines 55-57. Perez-Soler teaches that camptothecin displays cytotoxicity against tumor cells, as of Perez-Soler, column 1 lines 13-15 and 25-27.

The specific combination of features claimed is disclosed within the broad generic ranges taught by the reference but such “picking and choosing” within several variables does not necessarily give rise to anticipation. Corning Glass Works v. Sumitomo Elec., 868 F.2d 1251, 1262 (Fed. Circ. 1989). Where, as here, the reference does not provide any motivation to select this specific combination of variables specifically the carboxy form of camptothecin and a lipid vesicle comprising camptothecin with DOTAP, DOTMA, DOPE, and dielaidoyl phosphatidylcholine, anticipation cannot be found.

That being said, however, it must be remembered that “[w]hen a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious”. KSR v. Teleflex, 127 S.Ct. 1727, 1740 (2007) (quoting Sakraida v. A.G. Pro, 425 U.S. 273, 282 (1976)). “[W]hen the question is whether a patent claiming the combination of elements of prior art is obvious”, the relevant question is “whether the improvement is more than the predictable use of prior art elements according to their established functions.” (Id.). Addressing the issue of obviousness, the Supreme Court noted that the analysis under 35 USC 103 “need not

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seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” KSR v. Teleflex, 127 S.Ct. 1727, 1741 (2007). The Court emphasized that “[a] person of ordinary skill is... a person of ordinary creativity, not an automaton.” Id. at 1742.

Consistent with this reasoning, it would have obvious to have selected various combinations of various disclosed ingredients specifically the carboxy form of camptothecin and a lipid vesicle comprising camptothecin with DOTAP, DOPE, and dielaidoyl phosphatidylcholine from within a prior art disclosure, to arrive compositions “yielding no more than one would expect from such an arrangement”.

Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Perez-Soler et al. (US Patent 5,834,012) as applied to claims 24-27, 29, 31, 32, 34, 35 and 54 above, and further in view of Prakash et al. (US Patent 5,654,484).

Perez-Soler et al. (hereafter referred to as Perez-Soler) teaches the encapsulation of camptothecin in a liposome comprising cationic lipids, as shown above. Camptothecin is used as an anti-cancer agent, as shown supra.

Perez-Soler does not teach a cationic polymer.

Prakash et al. (hereafter referred to as Prakash) teaches that certain polyamine derivatives are effective therapeutic agents when administered to an animal suffering from neoplastic diseases, as of Prakash, column 1 lines 46-48.

It would have been *prima facie* obvious for one of ordinary skill in the art to have combined a polyamine, as of Prakash, with the liposome comprising DOTMA and camptothecin sodium of Perez-Soler. This is because camptothecin is an antitumor agent, as of Perez-Soler, column 1 lines 13-15 and 25-27, and polyamines have anticancer effects as well, as of Prakash, column 1 lines 46-48. Hence, both camptothecin and polyamines have are used for anti-neoplastic purposes. Generally, it is *prima facie* obvious to combine two compositions, each of which is taught by the prior art to be useful for same purpose, in order to form a third composition to be used for the very same purpose. The idea for combining them flows logically from their having been individually taught in the prior art. See MPEP 2144.06.

### ***Conclusion***

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 7 October 2009 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ISAAC SHOMER whose telephone number is (571)270-7671. The examiner can normally be reached on 8:00 AM - 5:00 PM Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on (571)272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/I. S./

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Examiner, Art Unit 1612

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612